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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/281,674	03/30/99	BUJARD	BBI-013030N2

000959
LAHIVE & COCKFIELD
28 STATE STREET
BOSTON MA 02109

HM12/0523

EXAMINER
SHUKLA, R

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 05/23/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

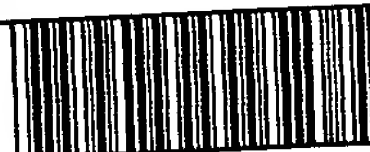
Application No.
09/281,674

Applicant(s)

Bujard et al

Examiner
Ram Shukla

Group Art Unit
1632



☒ Responsive to communication(s) filed on Mar 6, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-6, 9-14, and 17-19 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☒ Claim(s) 1-6, 9-14, and 17-19 is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

☐ Claims _____

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Part of Paper No. 9

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DETAILED ACTION

1. Amendment filed 3-6-00 (paper #8) has been entered.
Claims 7, 8, 15, and 16 have been canceled.
New claims 18 and 19 have been entered.
Claims 1-6, 9-14, 17-19 are under consideration in the instant application.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim 1-6, 9-14, and 17-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,888,981. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention of the instant application can not be practiced without infringing on the invention of the cited patent.

In the currently presented format, claims 1 and its dependent claims (2-5) are directed to a method for regulating expression of a tet-operator linked gene in a cell of a subject, wherein the tet operator linked gene and the tetracycline controllable transactivator tTA which is operably linked to an eukaryotic transcriptional transactivator polypeptide, are introduced in the cells as separate nucleic acid molecules (that is they are not covalently linked to each other in one construct and the concentration of tetracycline or its analog are modulate for regulating the gene expression. Claims 2-5 limit the Tet repressor to Tn10 while the eukaryotic transcriptional transactivator polypeptide is limited to HSV vp16, the tTA encoding molecule is integrated in the

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genome of the cell randomly or at a predetermined location. Claim 6 limits the method of claim 1 wherein the tTA encoding nucleic acid is introduced in a cell in vitro or ex vivo and then administered to the subject. Claim 9 limits the tetracycline analogs to anhydrotetracycline, doxycycline, or cyanotetracycline.

The invention of claim 10 and its dependent claims (11-14 and 17) is similar to that of the claim 1 except that in claim 10, a cell is obtained from a subject and in that isolated cell nucleic acids comprising tet operator linked gene and encoding tTA transcriptional transactivator is introduced using two different nucleic acids (not covalently linked).

In the method of Claim 18 and its dependent claims (2-5), both the tet operator repressor linked gene and the tTA transcriptional transactivator are comprised in one nucleic acid. Claims 2-7 limit the invention of claim 18, as they limit the invention of claim 1. Again claim 6, when dependent on claim 18, recites the same method but the nucleic acid is introduced in a cell ex vivo and then administered to the subject.

Claim 19, on the other hand, recites a function which has limitations similar to those of claim 18 except for the limitation that the cell is obtained from the subject and then the nucleic acid is introduced in the cell and the modified cell is then administered to the subject. Claims 11-14 and 17 limit the invention of claim 19 wherein the Tet repressor is Tn10 while the eukaryotic transcriptional transactivator polypeptide is limited to HSV vp16, the tTA encoding molecule is integrated in the genome of the cell randomly or at a predetermined location.

It is noted that the inventions of the cited patent and the instant application differ in only one respect, that is: the nucleic acids encoding the rTA transcriptional transactivator and the tet repressor operator are present in one construct (covalently linked together) or are present on two separate constructs. While the nucleic acids may be administered to a subject as one one construct or as two constructs, still the method remains the same i.e. the method of regulating the expression of a tet operator linked gene in a cell of a subject and both the nucleic acids are exogenously administered, wherein a tetracycline controllable transactivator binds to a tet operator sequences and regulates the expression of the gene linked to the tet operator.

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It would have been obvious to one of ordinary skill in the art to provide the tet operator linked gene and the tTA transactivator encoding gene on two separate constructs for regulating the expression of an exogenous gene in a subject because, this way a cell expressing a tTA transactivator can be used for regulating the expression of different exogenous genes.

4. No claim is allowed.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

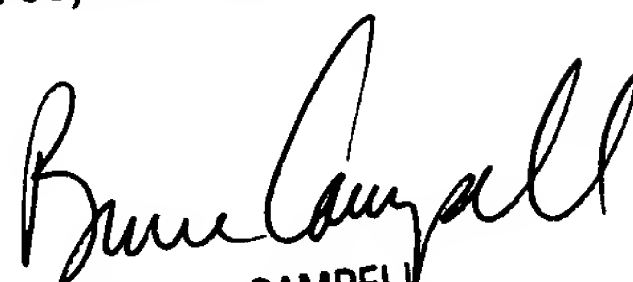
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Thursday and every other Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasmine Chambers, can be reached on (703) 308-2035. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 305-0196.

Ram R. Shukla, Ph.D.


BRUCE R. CAMPELL
PRIMARY EXAMINER
GROUP 1800